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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,486	04/07/2004	Zhi-Jian Yu	27529	7395

33357 7590 10/28/2008
ADVANCED MEDICAL OPTICS, INC.
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EXAMINER	
BROWN, COURTNEY A	
ART UNIT	PAPER NUMBER
1616	
MAIL DATE	DELIVERY MODE
10/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/820,486	YU ET AL.	
	Examiner	Art Unit	
	COURTNEY BROWN	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-25 and 27-57* is/are pending in the application.

4a) Of the above claim(s) *14-20 and 47-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,2,4-13,21-25,27-46 and 55-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/27/2004,1/10/2005,12/01/2005, and 11/21/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement of Receipt/Status of Claims

Receipt of Amendments/Remarks filed on June 24, 2008 is acknowledged. Claims 1, 2, 4-25, 27-57 are pending. Claims 3 and 26 stand cancelled. Claims 1, 2, 5.8,10,11,21,22,34, and 55 were amended. Claims 14-20 and 47-54 are withdrawn as being directed to a non-elected invention. Claims 1, 2, 4-13, 21-25, 27-46, and 55-57 are being examined for patentability.

Information Disclosure Statement

The Information Disclosure Statements (IDS) submitted on August 27, 2004, January 10, 2005, December 1, 2005, and November 21, 2007 have been considered by the examiner.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application

New Rejection(s) Necessitated by the Amendment filed on June 24, 2008

Claim Rejection(s) - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2,4-13, 22-25, and 27-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tusè et al. (US 6482799) in view of Araki et al. (US Patent Application 20030203849 A1) and Zhao (US 2003/0228393) further in view of Dykens et al. (S 2003/0105167 A1) and Huth (US 2004/0120916 A1).

Applicant Claims

Applicant claims a multipurpose solution and a multi-purpose solution for contact lens care comprising an aqueous liquid medium; 0.1 ppm to about 9.5 ppm

cetylpyridinium chloride; a second antimicrobial component that is selected from the group consisting of polyhexamethylene biguanide, a polyhexamethylene biguanide salt and polyquaternium-1; a viscosity inducing component selected from the group consisting of cellulose derivatives and mixtures thereof; a buffer component selected from the group consisting of boric acid/sodium hydroxide and boric acid/sodium borate buffers; a poly(oxpropylene)-poly(oxyethylene) block copolymer surfactant; a chelating component; a tonicity component; and taurine.

***Determination of the Scope and Content of the Prior Art* (MPEP § 2141.01)**

Tusè et al. teach an anti-microbial system suitable for formulations in a wide variety of ophthalmic solutions. These compositions are useful for storing, cleaning, or disinfecting a contact lens (abstract) and are stored as aqueous solutions (column 22, 60-end to column 24, lines 50-end). Additionally, Tusè et al. teach the use of antimicrobial preservative components such as cetylpyridinium chloride (CPC) and PHMB (polyhexamethylene biguanide) (column 17, lines 35-41); a viscosity adjusting agent such as cellulose derivatives and hydroxylproply methylcellulose (column 18, lines 46-55 and claim 58); a buffer component such as boric acid and sodium borate (column 15, 8-26); a chelating component such as EDTA (claims 10 and 11); and a tonicity component (claim 20).

Ascertainment of the Difference Between Scope of the Prior Art and the Claims (MPEP §2141.012)

The difference between the invention of the instant application and that of Tusè et al. is that the instant invention requires the use of a specific amount of CPC as opposed to being silent. For this reason, the teaching of Araki et al. is joined. Araki et al. teach the use of CPC as an antiseptic prepared in a concentration between 0.0001% (w/v) and 5% (w/v) (1-5000 ppm) ([0165]) in a topical ophthalmic agent (such as eye drops, ophthalmic ointments and the like) and a composition for a contact lens used for promoting lacrimal secretion ([0001]). Additionally, Araki et al. teach the use of polyoxyethylene-polyoxypropylene block copolymers as a gelling agents ([0127]).

Another difference between the invention of the instant application and that of Tusè et al. is that the instant invention requires the use of potassium chloride as a tonicity agent as opposed to cellulose derivatives. For this reason, the teaching of Dukens et al. is joined. Dykens et al., on page 5, paragraph 48 teach the use of sodium chloride and potassium chloride as tonicity agents in topical (e.g., eye drops) ophthalmic solutions.

A final difference between the invention of the instant application and that of Tusè et al. is that the instant invention requires the use of taurine as opposed to being silent. For this reason, the teachings of Huth and Zhao are joined. Huth teaches a contact lens care compositions comprising taurine which provide a cell membrane

protection function for ocular tissue cells during contact lens wear. Additionally, Zhao, in paragraphs 185-186, teach a nutritional supplement and herb remedy for helping vision and reducing eye problem that includes taurine.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to a person having ordinary skill in the art at the time of the invention was made to combine the teachings of Tusè et al., Araki et al., Zhao, Dykens and Huth to devise a multi-purpose contact lens care solution that contains all of the components disclosed by Tusè with the addition of taurine and the other noted agents. It would be obvious to combine these references because taurine is a non-essential amino acid that may impair vision when deficient in the human body. Additionally, as disclosed by Huth, on page 1, [0002], a contact lens care compositions comprising taurine provides cell membrane protection function for ocular tissue cells during contact lens wear. Thus, there is ample reason to want to include taurine in the composition of Tusè et al. Sodium chloride and potassium chloride are known tonicity agent. Thus, it is obvious to include well-known components in the known composition. Additionally, it is routine optimization for one of ordinary skill in the art to adjust ingredients to optimize the desired results. In this case, the viscosity inducing

component, the second antimicrobial component, the tonicity component, and the chelating component are all known in the art and it is simply a matter of routine optimization in an effort to optimize the desired results to arrive at the claimed amounts. It would be prima facie obvious to combine compositions each of which is taught by the prior art to be useful for the same purpose in order to form a final composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in prior art." In re Kerkhoven, 205 USPQ 1069 (C.C.P.A. 1980).Thus, combining Tusè with Araki et al., Zhao, Dykens and Huth, as claimed in the instant invention, sets forth prima facie obvious subject matter.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tusè et al. (US 6482799) in view of Araki et al. (US Patent Application 20030203849 A1), Zhao (US 2003/0228393), and Huth (US 2004/0120916 A1).

Applicant Claims

Applicant claims a multi-purpose contact lens disinfecting and cleaning solution comprising and aqueous liquid medium; cetylpyridinium chloride; a second microbial agent; a poly (oxpropylene)-poly (oxyethylene) block copolymer surfactant; and taurine.

***Determination of the Scope and Content of the Prior Art* (MPEP § 2141.01)**

The teaching of Tusè et al. is discussed above and hereby incorporated by reference.

Ascertainment of the Difference Between Scope of the Prior Art and the Claims (MPEP §2141.012)

The difference between the invention of the instant application and that of Tusè et al. is that the instant invention requires the use of a specific amount of CPC as opposed to being silent. For this reason, the teaching of Araki et al. is joined. Araki et al. teach the use of CPC as an antiseptic prepared in a concentration between 0.0001% (w/v) and 5% (w/v) (1-5000 ppm) ([0165]) in a topical ophthalmic agent (such as eye drops, ophthalmic ointments and the like) and a composition for a contact lens used for promoting lacrimal secretion ([0001]). Additionally, Araki et al. teach the use of polyoxyethylene-polyoxypropylene block copolymers as a gelling agents ([0127]).

Another difference between the invention of the instant application and that of Tusè et al. is that the instant invention requires the use of taurine as opposed to being silent. For this reason, the teachings of Huth and Zhao are joined. Huth teaches a contact lens care compositions comprising taurine which provide a cell membrane protection function for ocular tissue cells during contact lens wear. Additionally, Zhao, in paragraphs 185-186, teach a nutritional supplement and herb remedy for helping vision and reducing eye problem that includes taurine.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to a person having ordinary skill in the art at the time of the invention was made to combine the teachings of Tusè et al., Araki et al., Zhao, and Huth to devise a multi-purpose contact lens care solution that contains all of the components disclosed by Tusè et al. with the addition of taurine and the other noted components. It would be obvious to combine these references because taurine is a non-essential amino acid that may impair vision when deficient in the human body. Additionally, as taught by Huth, on page 1, [0002], a contact lens care composition comprising taurine provides cell membrane protection function for ocular tissue cells during contact lens wear. Thus, there is ample reason to want to include taurine in the composition of Tusè et al.. It would be prima facie obvious to combine compositions each of which is taught by the prior art to be useful for the same purpose in order to form a final composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in prior art." In re Kerkhoven, 205 USPQ 1069 (C.C.P.A. 1980). Thus, combining Tusè with Araki et al., Zhao, and Huth, as claimed in the instant invention, sets forth prima facie obvious subject matter.

Claims 34-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tusè et al. (US 6482799) in view of Araki et al. (US Patent Application 20030203849

A1), and Zhao (US 2003/0228393) further in view of Dykens et al. (S 2003/0105167 A1), and Huth (US 2004/0120916 A1).

Applicant Claims

Applicant claims a multi-purpose solution for contact lens care comprising an aqueous liquid medium; .1ppm to about 10ppm cetylpyridinium chloride; a non-ionic surfactant; a buffer component comprising boric acid; hydroxypropylmethyl cellulose (the viscosity inducing component); EDTA(a chelating component); a combination of sodium chloride and potassium chloride (the tonicity component); a second antimicrobial component selected from the group consisting of biguanides, biguanide polymers, monomeric and polymeric quaternary ammonium compound, salts and mixtures thereof; and taurine.

***Determination of the Scope and Content of the Prior Art* (MPEP § 2141.01)**

The teaching of Tusè et al. is discussed above and hereby incorporated by reference.

Ascertainment of the Difference Between Scope of the Prior Art and the Claims (MPEP §2141.012)

The difference between the invention of the instant application and that of Tusè et al. is that the instant invention requires the use of a specific amount of CPC as opposed to being silent. For this reason, the teaching of Araki et al. is joined. Araki et al. teach the use of CPC as an antiseptic prepared in a concentration between 0.0001% (w/v) and 5% (w/v) (1-5000 ppm) ([0165]) in a topical ophthalmic agent (such as eye drops, ophthalmic ointments and the like) and a composition for a contact lens used for promoting lacrimal secretion ([0001]). Additionally, Araki et al. teach the use of polyoxyethylene-polyoxypropylene block copolymers as a gelling agents ([0127]).

Another difference between the invention of the instant application and that of Tusè et al. is that the instant invention requires the use of potassium chloride as a tonicity agent as opposed to cellulose derivatives. For this reason, the teaching of Dukens et al. is joined. Dykens et al., on page 5, paragraph 48 teach the use of sodium chloride and potassium chloride as tonicity agents in topical (e.g., eye drops) ophthalmic solutions.

A final difference between the invention of the instant application and that of Tusè et al. is that the instant invention requires the use of taurine as opposed to being silent. For this reason, the teachings of Huth and Zhao are joined. Huth teaches a contact lens care compositions comprising taurine which provide a cell membrane protection function for ocular tissue cells during contact lens wear. Additionally, Zhao, in paragraphs 185-186, teach a nutritional supplement and herb remedy for helping vision and reducing eye problem that includes taurine.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to a person having ordinary skill in the art at the time of the invention was made to combine the teachings of Tusè, Araki et al., Zhao, Dykens and Huth to devise a multi-purpose contact lens care solution that contains all of the components disclosed by Tusè with the addition of taurine and the other noted components. It would be obvious to combine these references because taurine is a non-essential amino acid that may impair vision when deficient in the human body. Together with zinc, taurine is required for proper eye health and vision. Additionally, as disclosed by Huth, on page 1, [0002], a contact lens care compositions comprising taurine provides cell membrane protection function for ocular tissue cells during contact lens wear. Thus, there is ample reason to want to include taurine in the composition of Tusè. Sodium chloride and potassium chloride are known tonicity agents. Thus, it is obvious to include well-known components in the known process. Additionally, it is routine optimization for one of ordinary skill in the art to adjust ingredients to optimize the desired results. In this case, the viscosity inducing component, the second antimicrobial component, the tonicity component, and the chelating component are all known in the art and it is simply a matter of routine optimization in an effort to optimize the desired results to arrive at the claimed amounts. It would be prima facie obvious to combine compositions each of which is taught by the prior art to be useful for the same

purpose in order to form a final composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in prior art." In re Kerkhoven, 205 USPQ 1069 (C.C.P.A. 1980). Thus, combining Tusè with Araki et al., Zhao, Dykens and Huth, as claimed in the instant invention, sets forth prima facie obvious subject matter.

Claims 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tusè et al. (US 6482799) in view of Araki et al. (US Patent Application 20030203849 A1).

Applicant Claims

Applicant claims a multi-purpose solution comprising an aqueous liquid medium; about .1 to about 2 ppm cetylpyridimium chloride and a second microbial component selected from the group consisting of polyhexamethylend biguanide (PHMB), a polyhexamethylene buguanide salt and polyquaternium-1.

***Determination of the Scope and Content of the Prior Art* (MPEP § 2141.01)**

The teaching of Tusè et al. is discussed above and hereby incorporated by reference.

Ascertainment of the Difference Between Scope of the Prior Art and the Claims (MPEP §2141.012)

The difference between the invention of the instant application and that of Tusè et al. is that the instant invention requires the use of a specific amount of CPC as opposed to being silent. For this reason, the teaching of Araki et al. is joined. Araki et al. teach the use of CPC as an antiseptic prepared in a concentration between 0.0001% (w/v) and 5% (w/v) (1-5000 ppm) ([0165]) in a topical ophthalmic agent (such as eye drops, ophthalmic ointments and the like) and a composition for a contact lens used for promoting lacrimal secretion ([0001]). Additionally, Araki et al. teach the use of polyoxyethylene-polyoxypropylene block copolymers as a gelling agents ([0127]).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to a person having ordinary skill in the art at the time of the invention was made to combine the teachings of Tusè et al. and Araki et al. One would have been motivated to make this combination in order to receive the expected benefit of having a multi-purpose solution with an amount of antimicrobial agent that has been taught to be effective in an amount of 1-5000 ppm. Therefore, it would be prima facie obvious to combine compositions each of which is taught by the prior art to be useful for the same purpose in order to form a final composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in prior art." In re Kerkhoven, 205 USPQ 1069 (C.C.P.A. 1980).

Thus, combining Tusè with Araki et al., as claimed in the instant invention, sets forth prima facie obvious subject matter.

Examiner's Response to Applicant's Remarks

Applicant's arguments with respect to claims 1, 2, 4-13, 21-25, 27-46, and 55-57 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

None of the claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR Only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)?

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Courtney Brown, whose telephone number is 571-270-3284. The examiner can normally be reached on Monday-Friday from 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number or the organization where this application or proceeding is assigned is 571-273-8300.

Courtney A. Brown
Patent Examiner

Technology Center1600
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/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616